510(k) Summary

DEC - 8 2011

Owner's Name:	Soteira, Inc.
Address:	14 Tech Circle Natick, MA 01760
Telephone Number:	(508) 651-2611
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Contact Person:	John V. Hamilton, Director of Spinal Programs
Subject Device Name:	Shield Kyphoplasty System
Trade Name:	Shield Kyphoplasty System
Classification Name:	Polymethylmethacrylate (PMMA) Bone Cement
Product Code:	NDN
Regulation:	21 CFR 888.3027
Device Classification:	Class II device
Predicate Devices:	Stryker SpinePlex™ Bone Cement (K032945) Kyphon Kyphx® Inflatable Bone Tamp (K041454)

Device Description

The Soteira Shield Kyphoplasty System consists of a cement director (permanent implant), a delivery system (used to place the cement director within the vertebral body) and instruments that are used to achieve percutaneous access to the vertebral body and to create a cavity into which the cement director implant will be placed. The system is intended for use with commercially available PMMA bone cement.

Indications for Use

The Soteira Shield Kyphoplasty System (SKS) is intended to provide control of cement flow during injection of PMMA bone cement that has been cleared for use in vertebral augmentation for the treatment of acute, persistently painful (after a minimum of 6 weeks of conservative care), stable, anterior column osteoporotic compression fractures (wedge or concave) of the vertebrae at levels T4 – L5 in the adult spine.

Performance Testing

Pre-clinical testing included cadaveric bench testing, biocompatibility and MRI compatibility. The cadaveric bench tests consisted of static and cyclic mechanical testing of osteoporotic vertebral bodies treated with the Soteira Shield Kyphoplasty System and vertebroplasty. The Soteira Shield Kyphoplasty System demonstrated equivalent behavior under both test conditions. Biocompatibility testing was performed in accordance with ISO 10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing. This testing demonstrated the combination of the Soteira Shield implant and PMMA bone cement is biocompatible. The implant and bone cement have been tested for MRI compatibility and have been determined to be "MR-conditional" in accordance with the ASTM standard F2503-05 Standard Practice for Marking Medical Devices and Other Item for Safety in the Magnetic Resonance Environment.

Clinical testing consisted of a pilot study and a prospective randomized study using vertebroplasty as the control device. All subjects were diagnosed with osteoporotic compression fractures that had undergone conservative care for a minimum of 6 weeks or had

been hospitalized for pain. A total of 69 subjects and 102 levels were treated with the Soteira Shield Kyphoplasty System and 28 subjects and 38 levels were treated with the control device. Pain and functional testing demonstrated equivalent initial improvements and sustained benefits out to one year. The Soteira Shield Kyphoplasty System showed less assymptomatic leaks than the control (vertebroplasty). For the Soteira device adverse events included ; death, adjacent and distant level fractures, incomplete filling, refracture and retreatment of the treated levels while the control exhibited; death, adjacent and distant level fractures,and , refracture of a treated level

Conclusion

The Soteira Shield Kyphoplasty System has been demonstrated, through labeling, descriptive characteristics and performance testing data, to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Soteria, Inc.
% Delphi Medical Device Consulting, Inc.
Ms. Pamela Papineau
5 Whitcomb Avenue
Ayer, Massachusetts 01432

DEC 0 8 2011

Re: K093477
Trade/Device Name: Shield Kyphoplasty System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN
Dated: September 15, 2011
Received: October 24, 2011

Dear Ms. Papineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K093477

Device Name: Shield Kyphoplasty System

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Prescription Use __X___ (Per 21 CFR 801 Subpart D) OR Over-the -Counter Use ____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093477